



09-0408

Handwritten signatures and initials, including "A 1653" and "9/3/02".

Express Mail No.: ET473975565US - Date: September 3, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE APPLICATION OF:

SERIAL NO.:

FILED:

CASE NO.:

GROUP ART UNIT:

EXAMINER:

FOR:

Han et al.

09/728,653

December 1, 2000

PH-7118

1653

D. Lukton

ALPHA-KETOAMIDE INHIBITORS OF HEPATITIS C VIRUS
NS3 PROTEASE

Asst. Commissioner for Patents
Washington, D.C. 20231

**AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT AND TO
SEQUENCE LISTING REQUIREMENT**

Sir:

This amendment and response is submitted pursuant to the Office Action dated July 2, 2002 to which a response is due on or before August 2, 2002. A petition for one-month extension of time is herewith submitted, thus extending the due time for response until Monday, September 2, 2002, a national holiday. Applicant's response is thus considered timely. Claims 1-20 are under consideration. In response to the Office Action dated July 2, 2002, please amend the above-identified application, without prejudice, as follows.

IN THE SPECIFICATION

Please amend pages 171-179 as attached.

IN THE CLAIMS

Please cancel Claims 8-11 and 19-20.

RESPONSE TO RESTRICTION REQUIREMENT

Responsive to the Official Action dated July 2, 2002, Applicants elect with traverse, Group II, characterized in the restriction requirement for examination purposes only. In response to the requirement to elect a single disclosed species, Applicants elect, for initial examination purposes only, a compound of Formula:

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,653	12/01/2000	Wei Han	PH-7118	5964

24348 7590 07/02/2002

BRISTOL-MYERS SQUIBB PHARMA COMPANY
PATENT DEPARTMENT
P.O. BOX 4000
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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1653	5

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

BMS PATENT LAW

↓
FAXED
7/10/02

7/10/02
JUL 08 2002
Docketed Item RRRD
Due Date 8/2/02
Attorney SKL

already
DOCKETED: 7/10/02
Due Date: 8/2/02
No Action Required: SKL

Office Action Summary

Application No.
09/728,653

Applicant(s)
Han

Examiner
David Lukton

Art Unit
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 23, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

See, for example, the sequences on pages 171, 172, and 173.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

A restriction is imposed. First, however, the following subgenera are defined:

- ✓ G1: at least three of ✓A2, ✓A3, ✓A4, A5, A6 is a group other than a bond;
- × G2: at least three of ×A2, ×A3, ×A4, ✓A5, ✓A6 is a covalent bond;
- × G3: Q must contain Q1;
- ✓ G4: Q is either an amino acid, or $(\text{CHR}^{10})_n\text{Q}^2$.

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1, 8, 9, 12, 19 limited to G1 and G3.

2. Claims 1-6, 8, 12-16, 19 limited to G1 and G4. ^{B5}

3. Claims 1, 8, 9, 12, 19 limited to G2 and G3.

4. Claims 1-6, 8, 12-16, 19 limited to G2 and G4.

5. Claims 17-18, drawn to a method of using the compounds of Group 1.

6. Claims 17-18, drawn to a method of using the compounds of Group 2.

7. Claims 17-18, drawn to a method of using the compounds of Group 3.

8. Claims 17-18, drawn to a method of using the compounds of Group 4.

Neither of claims 10 or 11 is grouped. Claim 10 is dependent on claim 3. Claim 3, in turn, mandates that Q be limited to $(CHR^{10})Q^2$. In other words, based upon claim dependence alone, claim 3 precludes the possibility that Q be $(CHR^{10})Q^1$. Yet claim 10 defines variable Q^1 without defining variable Q^2 . Thus, it cannot be determined whether applicants intend for claim 10 to permit Q^1 to be present or not. The same situation holds in the case of claim 11, although claim 11 is improperly dependent for each of two separate reasons, the second reason being that it permits variable R^{10} to be hydrogen. In the event that claims 10 and 11 are amended so that their claim dependence is proper, these claims will be grouped accordingly. Claim 20 is not grouped because it is drawn

to a "use". Claim 7 is also not grouped. In the event that applicants elect one of Groups 1-4, claim 7 will be joined with that group.

The claimed inventions are distinct.

Inventions {1-4} and {5-8} are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). However, in the event that any of Groups 1-4 is elected, and claims therein found allowable, the corresponding method-of-use claims will be rejoined for further examination.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A "specie" is a specific compound, with all substituent variables and integer variables fully accounted for.

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Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800